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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,292	12/01/2003	Juan Armendariz Borunda	061537-0036US	4513

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	
MAIL DATE	**DELIVERY MODE**
09/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,292	ARMENDARIZ BORUNDA ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed 9-9-10 has been entered. Claims 22 and 24 have been amended. Claims 22 and 24 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "wherein the adenoviral vector is the vector contained in ATCC Deposit No. PTA-10532" in claim 22 is vague and renders the claim indefinite. There is no description of what is contained in the ATCC Deposit No. PTA-10532. The submitted letter from ATCC only reveals that 25 vials are contained in the PTA-10532, however, it is unclear what kind of material or adenoviral vector is contained in those 25 vials. The amendment to the specification on page 17 fails to clarify what kind of material or adenoviral vector is contained in those 25 vials other than pcDNA-MMP-8 with CMV promoter. Claim 24 depends from claim 22 but fails to clarify the indefiniteness.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22 and 24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 4-22-10. Applicant's arguments filed 9-9-10 have been fully considered but they are not persuasive.

Applicant argues that the claims are amended to read on hepatic fibrosis and the specification provides guidance and evidence that the target of the administered viral particles is primarily and predominantly the liver. The specification demonstrated that the claimed composition comprising the viral particles targets the liver almost exclusively and the specific vector is contained in ATCC Deposit No. PTA-10532 (amendment, p. 4-5). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 4-22-10. As discussed above, it is unclear what kind of material or adenoviral vector is contained in the ATCC Deposit No. PTA-10532 other than pcDNA-MMP-8 with CMV promoter, therefore, it is assumed that the recombinant adenoviral vector expresses a therapeutic protein. The claims encompass treating hepatic fibrosis in a subject by delivering a recombinant adenoviral vector expressing a therapeutic protein under the control of a promoter to liver via intravenous administration in vivo. The specification fails to provide adequate guidance and evidence for delivering a recombinant adenoviral vector expressing a therapeutic protein, such as MMP-8, under the control of a promoter via intravenous administration in vivo such that sufficient therapeutic protein can be obtained so as to provide therapeutic effects in target organs for

treating hepatic fibrosis in a subject. The adenoviral vector can induce both cell-killing "cellular" immune response and the antibody-producing "humoral" immune response from the host. The virally infected cells can be killed by cytotoxic T lymphocytes and the humoral response results in the generation of antibodies against adenoviral proteins. Although infusion of Ad5gal vector by iliac vein shows that the main target organ of the infused adenoviral vector is the liver, however, there is no evidence of record that shows intravenous administration of the claimed composition would provide sufficient therapeutic protein at target site so as to provide therapeutic effects in target organs for treating hepatic fibrosis in a subject. Absent specific guidance, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 22 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 41 and 42 of copending Application No. 11/064,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although drawn to different scope, they encompass the same invention and obvious variants thereof.

Claim 22 of the instant invention is directed to a composition to treat hepatic fibrosis in a subject comprising a therapeutically effective amount of unitary doses of between 10^7 and 10^{14} adenoviral particles of a recombinant adenoviral vector, wherein said adenoviral vector is the vector contained in ATCC Deposit No. PTA-10532, and a pharmaceutically compatible carrier.

Claims 22, 41 and 42 of Application No. 11/064,504 ('504) are directed to a recombinant adenoviral vector contained in ATCC Deposit No. PTA-10532, wherein the recombinant adenoviral vector encodes a latent human metalloprotease MMP-8 under the control of a

cytomegalovirus (CMV) promoter, a composition comprising the recombinant adenoviral vector and a pharmaceutically acceptable carrier, and the composition comprises a unitary dose of between 10^7 and 10^{14} adenoviral particles.

Since the recombinant adenoviral vector encodes a latent human metalloprotease MMP-8 under the control of a cytomegalovirus (CMV) promoter is contained in ATCC Deposit No. PTA-10532 and the intended use of the claimed composition of the instant invention does not carry weight in 35 U.S.C.103(a) rejection, claim 22 of the instant invention would be obvious to one of ordinary skill in the art at the time of the invention in view of the disclosure of '504.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen
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